

### III. REMARKS

This document is being submitted in response to the final Office Action mailed by the Patent Office on August 25, 2006. In the present application, claims 1-4, 6-8, and 10-13 are pending, claims 5 and 9 have been cancelled without prejudice, claims 12-13 have been withdrawn from consideration, and claims 1-4, 6-8, and 10-11 stand as rejected by the Patent Office. In Response to the Office Action of August 25, 2006, the Applicant has filed a Request for Continued Examination (RCE) and further amended claims 1-4, 6-8, and 10-11. The Applicant respectfully requests reconsideration of the claims in light of the amendments and remarks made herein.

#### 35 U.S.C. §103(a)

On pages 2-3 of the Office Action of August 25, 2006, the Patent Office states that claims 1, 3, and 5-7 are rejected under 35 U.S.C. §103(a) as being unpatentable over Smith (U.S. Pat. No. 6,761,702) in view of Shu (U.S. Pat. No. 6,918,517). On pages 3-4 of the Office Action, the Patent Office states that claims 2, 4, and 8-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Smith in view of Shu, and further in view of Ouelette (U.S. Pat. No. 4,842,580). On page 4 of the Office Action, the Patent Office makes further reference to Hawks (U.S. Pat. No. 4,943,285) with regard to claims 2, 4, and 8-11. For purposes of more clearly defining the invention and correcting certain grammatical inconsistencies, claims 1-4, 6-8, and 10-11 have been further amended. For the reasons stated below, the amended claims are believed to define patentably over the § 103 references cited by the Patent Office.

MPEP 2142 provides that to establish a *prima facie* case of obviousness, three basic criteria must be met: (i) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings; (ii) there must be a reasonable expectation of success; and (iii) the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and must not be based on the Applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). The Applicant argues

that the claims, as amended, do not permit a finding of *prima facie* obviousness in the present application because the prior art references do not teach nor suggest all the claim limitations of the Applicant's claimed invention, and/or there is no reasonable expectation of success in combining the teachings of the references.

The Applicant asserts that in view of the amendments made to independent claims 1, 3, and 8, Smith and Shu do not, either individually or in combination, teach nor suggest all of the Applicant's claim limitations as required by MPEP 2142 for a finding of obviousness. More specifically, the Applicant's colon hydrotherapy device provides a substantially cylindrical housing that includes two separate and distinct chambers formed in the body of the housing itself. The claim element of "a dividing wall formed between the first and second chambers for completely separating the first chamber from the second chamber" has been added to independent claims 1, 3, and 8 to further emphasize this important and non-obvious difference between the claimed invention and the cited references. These structural features are all clearly visible in Applicant's FIG. 3b. Irrigation fluid enters the Applicant's device through the first chamber and waste material exits the device through the second chamber. The dividing wall prevents any contamination of the incoming irrigation fluid with waste material exiting the device through the second chamber. The device taught by Smith provides a tubular body (10) that includes only a single internal passage (22) formed integrally with the body (10). Smith specifically states in Column 3, lines 56-60 that **"a medical grade PVC hose 26 ... is inserted through the seal 28 to extend through the tubular body 10 and the opening 16 into the colon of the patient."** Thus, there is only one chamber in the housing of Smith's device, and a length of hose (see Smith, Fig. 3), must be inserted into the tubular body (10) to introduce irrigation fluid into the colon of a patient. Clearly, the device taught by Smith does not include the element of a housing that has two separate and distinct chambers formed therein, and none of the other references cited by the Patent Office teach this feature of the Applicant's claimed invention.

With further regard to claim limitations not taught nor suggested by the prior art references (as required by MPEP 2142), the Applicant's claimed invention (as amended)

includes: “a nozzle attached to one end of the housing, wherein the nozzle further includes: a plurality of trapezoidal outlets formed in the anterior portion thereof, and an aperture formed in the posterior portion thereof, wherein the aperture connects the plurality of outlets to the first chamber.” Neither Shu, nor any of the other §103 references cited by the Patent Office includes a nozzle having trapezoidal water outlets. As also taught by amended claim 1, the Applicant’s invention further includes “a source of pressurized water in fluid communication with the first chamber, wherein the pressurized water enters the first chamber, travels through the first chamber, and exits the colon hydrotherapy device through the plurality of outlets formed around the anterior portion of the nozzle, and wherein the combination of the pressurized water and the trapezoidal shape of each outlet in the plurality of outlets produces a high-pressure vortex of water for colon cleansing”. Thus, the unique trapezoidal shape of the nozzle outlets combined with the pressurized water source creates a high-pressure fluid vortex for dissolving or breaking-up solid matter found within the large intestine. None of the §103 references cited by the Patent Office teaches a colon hydrotherapy device or system that creates a high-pressure water vortex such as that taught by the Applicant (see paragraph 0029 of Applicant’s specification).

Despite the Patent Office’s assertion on Page 2 of the present Office Action (paragraph 3), Smith makes no mention of “high pressure” colonic irrigation. The low-pressure device taught by Shu includes a nozzle with elongated grooves (614) that allow water to flow from the nozzle (see Col. 3, lines 41-45). The Applicant’s claim limitation of a nozzle having a plurality of trapezoidal outlets is completely absent from Shu and from the other cited references. Furthermore, Shu actually teaches away from using a high-pressure vortex. In Column 3, lines 41-45, Shu states that *“the water flows along the channel 613 to the passage 632 and is then directed to flow along the elongated grooves 614 from the proximate ends 6141 towards the distal ends 6142 in gentle water streams for cleansing the anal canal 70 and the rectum 80.”* Thus, combining the “high pressure” device of Smith with the nozzle of Shu, which is clearly intended to create “gentle water streams”, would result in a non-functional device, meaning that there is no reasonable expectation of success as required by MPEP 2142. The Applicant, therefore, asserts that the claimed invention is not obvious over Smith in view of Shu and respectfully requests reconsideration of claims 1, 3, and 8 and their associated dependent claims.

The Applicant also asserts that in view of the amendments made to independent claims 1, 3, and 8, and to dependent claims 2, 4, 10-11 that Smith, Shu, Ouelette, and Hawks do not, either individually nor in combination, teach or suggest all of the Applicant's claim limitations as required by MPEP 2142. More specifically, the Applicant's claimed device provides an obturator 31 (i.e., an insertion rod) that further includes a rounded tip formed at one end and having a groove 32 that corresponds to the location of the first chamber within the cylindrical housing (see Applicant's FIGS. 4a and 4b). A planar grasping member 35 formed at the other end of the insertion rod and further includes at least one stabilizing notch 36 (see Applicant's FIG. 2) formed therein. The design of obturator 31 is specific to the internal and external geometry of the cylindrical housing, and despite the Patent Office's assertions on pages 3-4 of the Office Action, neither of the insertion rods taught by Oulette or Hawks includes a grooved tip or a notched grasping member that engages the body of the cylindrical housing as shown in Applicant's FIG. 1a. Thus, because these limitations are also completely absent from the cited references, the cited references do not teach all of the claim limitations as required by MPEP 2142. Thus, the Patent Office's rejection of claims 2, 4, 10-11 under §103 is improper and should be withdrawn.

#### Conclusion

In light of the amendments made to the claims and the arguments presented above, the Applicant asserts that independent claims 1, 3, and 8 are not obvious in view of the cited references and that these claims define patentably over the art cited by the Patent Office. Because claims 2, 4, 6-7, and 10-11 are independent claims that depend from either claim 1, 3, or 8, the Applicant asserts that these claims are also patentable over the cited references. For the reasons set forth herein, this application is believed to be in condition for allowance. Favorable reconsideration of this application is respectfully requested.

Respectfully submitted,

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